



Long Term Care NEWSLETTER

Indiana State Department of Health

ISDH Long Term Care
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In Today's Issue:

- CMS Updates
- Updated Contact List
- Influenza Vaccinations
- Drug Recall
- Newsletter Update

CMS Updates

The Centers for Medicare and Medicaid Services (CMS) periodically issues survey and certification letters to provide guidance on health care provider issues. CMS has issued one letter pertaining to certified comprehensive care facilities (nursing homes).

CMS Survey and Certification Memo 09-11: Release of Report: "Freedom from Unnecessary Physical Restraints: Two Decades of National Progress in Nursing Home Care" (11/7/08)

CMS [Survey and Certification Memo 09-11](#) discusses a report on unnecessary physical restraints. Attached to the memo is a report that evaluates the efforts to reduce the use of physical restraints after Congressional Passage of the 1987 Nursing Home Reform Act. Because of the hard work of practitioners, providers, advocates, and government agencies, the percentage of nursing home residents physically restrained daily substantially declined from 21.1 percent in 1991 to less than 5.0 percent in 2007.

Update on Agreements Between Nursing Homes and Hospices:

CMS Region V provided a response to a question from a provider association staff member. The Regional Office asked CMS Central Office about new issuances related to SNF/NFs, hospices and ESRDs. The following information was received from Central Office.

There is a regulation for SNF/NFs in process in CMS that is a companion to the hospice regulation in the area of written agreement between a nursing home and a hospice. The SNF/NF regulation will contain language similar to the hospice regulation. CMS does not have information as to when it will go out as a proposed rule. Additionally, CMS is going to be moving the language in Appendix P that identifies how to survey for hospice and ESRD and placing them in the guidance at F309. This will take place when the interpretive guidance at F309 for Pain Management is added, which is projected to be sometime before the end of this calendar year. There was no information about sending these changes out for review.

Updated Contact List

To assist individuals in reaching the appropriate person at the Indiana State Department of Health, the Division of Long Term Care provides an [updated contact list](#).

Importance of Influenza Vaccination for Health Care Personnel

The following article appeared in the FDA Patient Safety News. To view Webcasts, visit the FDA Web site at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/transcript.cfm?show=81#4>.

As the flu season approaches, FDA is urging healthcare facilities to ensure that influenza vaccination programs are available for their personnel. Vaccinating healthcare workers will decrease the likelihood that they will contract influenza, and also decrease the chance that they will infect others. This is especially important because these personnel often provide care to patients at high risk of serious and even fatal complications if they contract influenza. Of course another benefit of vaccinating staff is that it also protects their families from getting the disease.

Persons who should be immunized include physicians, nursing staff, pharmacists, technicians, emergency personnel, dental personnel, and students. The list also includes those who are not directly involved in patient care, such as clerical, dietary, housekeeping, and security staff.

CDC estimates that only 40% of health care workers get the flu vaccine each year. Yet studies have shown that low vaccination rates among health care personnel contribute to influenza outbreaks in healthcare facilities, and this needlessly puts patients at risk. It has also been shown that there is a lower incidence of nosocomial influenza cases in those facilities where staff vaccination rates are higher.

For example, in one study, influenza cases and immunization records at a single hospital were followed for 12 years. Over that time, staff vaccination coverage increased from 4 percent to 67 percent, while influenza cases among the staff decreased from 42 percent to 9 percent. At the same time, nosocomial influenza cases among hospitalized patients decreased from 32 percent to zero.

So educate staff about the importance of getting a flu shot, and try to ensure that vaccination programs are available for them. Fall is the best time to be immunized, but getting the vaccine in the winter months is also recommended.

Additional Information:

CDC. Health Care Personnel Initiative to Improve Influenza Vaccination Toolkit. September 2008.
<http://www.hhs.gov/ophs/programs/initiatives/vacctoolkit/index.html>

FDA/CBER Influenza Virus Vaccine 2008-2009. October 29, 2008.
<http://www.fda.gov/cber/flu/flu2008.htm>

Voluntary Drug Recall

The FDA posted the following notice of a drug recall on November 7, 2008.

ETHEX Corporation Initiated Nationwide Voluntary Recalls of Specific Lots of Five Generic Products Due to the Potential for Oversized Tablets

Propafenone HCl Tablets - 150 mg, 225 mg, and 300 mg
Isosorbide Mononitrate Extended Release Tablets – 30 mg and 60 mg
Morphine Sulfate Extended Release Tablets - 15 mg
Morphine Sulfate Immediate Release Tablets - 15 mg and 30 mg
Dextroamphetamine Sulfate Tablets - 10 mg

Contact:

FOR IMMEDIATE RELEASE -- St. Louis, MO- November 7, 2008 – ETHEX Corporation announced today that it has voluntarily recalled to the consumer level specific lots of five generic /non-branded products that it markets. These lots have been recalled as a precaution, due to the possibility that they may contain oversized tablets. Oversized tablets may contain more than the intended levels of the active drug ingredient, which could result in patients receiving as much as about twice the expected dosage of these drugs.

Overdoses of Propafenone HCl, Isosorbide Mononitrate, Morphine sulfate and Dextroamphetamine Sulfate can have serious or life-threatening consequences. In the case of Propafenone HCl, these consequences can include arrhythmias (irregular heartbeat) and low blood pressure. In the case of Isosorbide Mononitrate, these consequences can include fainting and low blood pressure. In the case of Morphine Sulfate, these consequences can include respiratory depression (difficulty or lack of breathing) and low blood pressure. In the case of Dextroamphetamine Sulfate, these consequences can include rapid heart rate and high blood pressure.

The lots involved in the recall were all shipped prior to May 22, 2008 and are as follows:

Propafenone HCl Tablets, 150 mg: Lots: 73761, 78184, 79373, 81240, 81241, 81242, 83470, 84357, 90525, and 90526 with expiration dates ranging from 3/2009 to 3/2011

Propafenone HCl Tablets, 225 mg: Lots: 71720, 74831, 76014-15, 81243-45, 89731, 90527-29, and 90657 with expiration dates ranging from 3/2009 to 2/2011

Propafenone HCl Tablets, 300 mg: Lots: 72834, 76016-18, 81246, 89092, 89732, 90530, 90532, and 91641-42 with expiration dates ranging from 6/2009 to 3/2011

Isosorbide Mononitrate Extended Release Tablets, 30 mg: Lots: 62355, 66423, and 68102 with expiration dates ranging from 11/2008 to 8/2009

Isosorbide Mononitrate Extended Release Tablets, 60 mg: Lots: 63466, 66034, 67351, and 67354 with expiration dates ranging from 12/2008 to 11/2009

Morphine Sulfate Extended Release Tablets, 15 mg: Lots: 81175, 82514-16, 89660, 89664, 89667, 90249-51, and 91687 with expiration dates ranging from 12/2008 to 2/2010

Morphine Sulfate Immediate Release Tablets, 15 mg: Lots: 77852-54, 81746, 82519-20, 84113, and 90276-78 with expiration dates ranging from 9/2009 to 1/2011

Morphine Sulfate Immediate Release Tablets, 30 mg: Lots: 75093, 77855-57, 82297, 82521-22, 87239, 88925, and 90288-98 with expiration dates ranging from 8/2009 to 3/2011

Dextroamphetamine Sulfate Tablets, 10 mg: Lots: 73934, 75892, 77945, 81137, 86320 with expiration dates ranging from 6/2009 to 5/2011

The 150 mg Propafenone Hydrochloride Tablets is a white, scored round film coated tablet with "ETH" on one side and "331" with a bisect on the reverse. The 225 mg Propafenone Hydrochloride Tablets is a white, scored round film coated tablet with "ETH" on one side and "332" with a bisect on the reverse. The 300 mg Propafenone Hydrochloride Tablets is a white, scored round film coated tablet with "ETH" on one side and "333" with a bisect on the reverse.

The 30 mg Isosorbide Mononitrate Extended Release Tablet is an oval, reddish-pink, film-coated tablet with a debossed "E" bisecting "30" on one side and bisect on the other side. The 60 mg Isosorbide Mononitrate Extended Release Tablet is an oval, yellow film-coated tablet with a debossed "E" bisect "60" on one side and bisect on the other side.

The 15 mg Morphine Sulfate Extended Release Tablet is a green oval tablet with "15" on one side and an "E" on the reverse. The 15 mg Morphine Sulfate Immediate Release Tablet is a round brown tablet with a "15" on one side and an "ETH" on the reverse. The 30 mg Morphine Sulfate Immediate Release Tablet is a capsule shaped brown tablet with "30" on one side and an "ETHEX" on the reverse.

The 10 mg Dextroamphetamine Sulfate Tablet is a round, flat-face, bevel edge, orange mottled tablet debossed "ETHEX" and "312" on one side and double-scored on the other side.

ETHEX Corporation has initiated recall notifications to wholesalers and retailers who have received any inventory of the recalled product lots with instructions for returning the recalled products. The notification also includes instructions for the retailers/pharmacies to contact consumers who were dispensed these drugs for replacement of the product and/or refund. If the wholesalers and retailers have not already done so, they are urged to contact the number below regarding procedures for returning the recalled products. If consumers have any questions about the recall, they should call the number listed below for customer inquiries, their physician, their pharmacist or other health care provider.

Consumers who experience any adverse reactions to these drugs should contact their physician and/or healthcare provider immediately.

Any customer inquiries related to this action should be addressed to ETHEX Customer Service at 1-800-748-1472, or fax to ETHEX Customer Service at 314-646-3751 or sent via email to: customer-service@ethex.com with representatives available Monday through Friday, 8:00 am to 5:00 pm Central Standard Time (CST).

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration (FDA).

Any adverse reactions experienced with the use of these products, and/or quality problems may also be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by Fax at 1-800-FDA-0178, by mail at MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch.

Newsletter Update

Last month the Indiana State Department of Health and University of Indianapolis Center for Community and Aging implemented the Indiana Pressure Ulcer Initiative. Over the past two weeks initial learning sessions were completed for participating facilities. An important part of the initiative is providing information to participants. This electronic newsletter will be used to disseminate pressure ulcer information throughout this initiative.

While this newsletter will continue to be published on approximately a bi-weekly basis, at least one issue every month will focus specifically on the Indiana Pressure Ulcer Initiative. The purpose will be to report the progress of the initiative and provide valuable information to all facilities. The information may be beneficial not only those active in the Indiana Pressure Ulcer Initiative but other facilities and individuals.

There is no limit to the number of individuals that can register for this newsletter and there is no cost to subscribe. We particularly encourage staff and families of facilities participating in the pressure ulcer initiative to register for this newsletter. If not already registered, we encourage the staff of all facilities to register to ensure access to valuable information.

You can subscribe the long term care newsletter by going to the following ISDH Web site, <http://www.in.gov/isdh/20511.htm>, and scroll down to the newsletter subscription information. The [attached flyer](#) also provides the subscription process. You may also forward this newsletter to interested individuals at the link at the bottom of this newsletter.

That is all for this week. Best wishes for the coming week.

Terry Whitson
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